ANDA 75-297 October 10, 2000

Zenith Goldline Pharmaceuticals, Inc.
Attention: Patricia Jaworski
140 Legrand Avenue
Northvale, NJ 07647

Dear Madam:

This is in reference to your abbreviated new drug application dated December 30, 1997, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Paclitaxel Injection, 6 mg/mL (packaged in 5 mL, 16.7 mL and 25 mL multiple dose vials).

Reference is also made to your amendments dated December 6 and December 14, 1999; May 9, June 9, June 21, August 15 and September 19, 2000.

We have completed the review of this abbreviated application and have concluded that, based upon the information you have presented to date, the drug is safe and effective for use as recommended in the submitted labeling. Therefore, the application is **tentatively approved**. This determination is based upon information available to the Agency at this time (i.e., information in your application and the status of current good manufacturing practices of the facilities used in the manufacturing and testing of the drug product) and is therefore subject to change on the basis of new information that may come to our attention.

The listed drug product referenced in your application is subject to periods of patent protection which expire on August 3, 2012, (U.S. Patents No. 5,641,803 [the '803 patent], 5,670,537 [the '537 patent]) and March 9, 2013 (U.S. Patent No.
5,496,804 [the '804 patent]). Your application contains a patent certification under Section 505(j)(2)(A)(vii)(IV) of the Act stating that your manufacture, use, or sale of this drug product will not infringe on these patents. Section 505(j)(5)(B)(iii) of the Act provides that approval of an abbreviated application shall be made effective immediately unless an action is brought before the expiration of forty-five days from the date the notice provided under paragraph

(2)(B)(I) is received by the owner of the new drug application (NDA) for the referenced listed drug product and the patent holder. You have notified FDA that Zenith Goldline Pharmaceuticals, Inc. has complied with the requirements of Section 505(j)(2)(B) of the Act and that Bristol-Myers Squibb initiated a suit against Zenith Goldline Pharmaceuticals, Inc. and Ivax Corporation in the United States District Court for the District of New Jersey (Bristol-Myers Squibb Company v. Zenith Goldline Pharmaceuticals, Inc. and Ivax Corporation, Civil Action No. 97-6050). You have notified the Agency that on August 17, 2000, the 30 month period has expired precluding the Agency from approving this product and the court has not extended this period.

Please note that an abbreviated application for Paclitaxel Injection, 6 mg/mL, containing a Paragraph IV Patent Certification was accepted for filing by this Office prior to the filing of your application. This application, submitted by Baker Norton Pharmaceuticals, Inc., received final approval on September 15, 2000. Consequently, Baker Norton Pharmaceuticals is eligible for 180-days of generic drug market exclusivity. Your application will be eligible for final approval beginning one hundred and eighty (180) days after the first commercial marketing of the drug by Baker Norton Pharmaceuticals, Inc. We refer you to the Agency's guidance document entitled "180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments" (June 1998), for additional information.

Because the Agency is granting a tentative approval for this application, please submit an amendment at least 60-days but not more that 90-days prior to the date you believe your application will be eligible for final approval. This amendment should identify changes, if any, in the conditions under which the drug product was tentatively approved, and should include updated information such as final printed labeling, chemistry, manufacturing and controls data as appropriate. Alternatively, an amendment should be submitted stating that no changes have been made to the terms of the application since the date of tentative approval. This submission should be designated clearly in your cover letter as a MINOR amendment. In addition to, or instead of, the amendment requested above, the Agency may, at any time prior to the final date of approval, request that you submit an amendment containing the information described above.

Any changes in the conditions outlined in this abbreviated

application and the status of the manufacturing and testing facilities' compliance with current good manufacturing procedures are subject to Agency review before final approval of the application will be made.

In addition to, or instead of, the amendments referred to above, the Agency may, at any time prior to the final date of approval, request that you submit amendments containing the information requested above.

Failure to submit either or both amendments may result in rescission of this tentative approval determination, or delay in issuance of the final approval letter.

The drug product that is the subject of this abbreviated application may not be marketed without final Agency approval under section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug before the effective final approval date is prohibited under section 501 of the Act. Also, until the Agency issues the final approval letter, this drug product will not be listed in the Agency's "Approved Drug Products with Therapeutic Equivalence Evaluations" list.

The amendment should be designated as a MINOR AMENDMENT in your cover letter. Before you submit the amendment, please contact Michelle Dillahunt, Project Manager, at (301) 827**B**5848, for further instructions.

The introduction or delivery for introduction into interstate commerce of the drug before the effective approval date is prohibited under 21 U.S.C. 331(d).

Sincerely yours,

Gary Buehler
Acting Director
Office of Generic Drugs
Center for Drug Evaluation and Research